AMENDMENT TO RULES COMMITTEE PRINT 117–54

OFFERED BY MS. HERRELL OF NEW MEXICO

At the end of title LVIII, add the following:

SECTION _____. REPORT AND RECOMMENDATION ON BARRIERS TO DOMESTIC MANUFACTURING OF MEDICAL PRODUCTS.

(a) REPORT TO CONGRESS.—Not later than 180 days after the date of the enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary''), acting through the Commissioner of Food and Drugs, shall submit to Congress a report on barriers, including regulatory inefficiencies, to domestic manufacturing of active pharmaceutical ingredients, finished drug products, and devices that are—

(1) imported from outside of the United States; and

(2) critical to the public health during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act (42 U.S.C. 247d).

(b) CONTENT.—Such report shall—

(1) identify factors that limit the manufacturing of active pharmaceutical ingredients, finished drug products, and devices described in subsection (a); and

(2) recommend specific strategies to overcome the challenges identified under paragraph (1).

(c) IMPLEMENTATION.—The Secretary may, to the extent appropriate, implement the strategies recommended under subsection (b)(2).

(d) DEFINITION.—In this section, the term ''active pharmaceutical ingredient'' has the meaning given to such term in section 744A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j–41).